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EXAMINER
HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
1637	6

DATE MAILED: 08/01/2002

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,512	Applicant(s) PELLETIER, JERRY	
	Examiner Shar Hashemi	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-28 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-28 and 31* is/are rejected.

7)☒ Claim(s) *8,25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Amendment Changes

1. Applicant's amendment, filed on January 28, 2002 (Paper No. 8) is acknowledged.

Claims 10, 11, 29, & 30 have been cancelled.

Claims 4, 8, 14, 17, 20, 24, & 27 have been amended.

Claims 1-9, 12-28, & 31 are pending and being acted upon presently.

Claim Objections

2. Claims 8 & 25 are objected to because of the following informalities: Nucleocasid (page 29, line 5) and systhesis (page 32, line 3) are misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 13, 15-17, 21-28 & 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The term "flWT1(GNRA)2" renders claims 13 & 16 indefinite. It is unclear as to whether the term "flWT1(GNRA)2" refers to the weight, length, or loop sequence of RNA.

B) The lack of **active method steps** renders claims 1-9, 15-17, 21-28 & 31 indefinite. Claims must be rewritten to include active steps.

C) The term "a polymerase" in claims 1 & 31 is confusing because the preamble recites a method of using a specific RNA-dependent DNA polymerase while the active step utilizes a general polymerase.

D) Claims 6, 16, 20 & 25 recite the limitations "the nucleic acid polymerization mixture" (claims 6 & 25), "the reverse transcriptase" (claim 6), "said RNA" (claim 16), "the chaperone protein Ncp7" (claim 20), "the DNA polymerase" (claim 25). There is insufficient antecedent basis for this limitation in the claim.

E) The term "significant" in claims 6 & 25 is a relative term which renders the claims indefinite. The term "significant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of these claims cannot be established because several parameters determine "significant" and because no single set of conditions is recognized by the art as being "significant" to the exclusion of all other conditions, the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-9, 12, 14-15, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legerski (US 6, 406, 891 B1 June 18, 2002) in view of Allen et al (US 5, 654, 151 August 5, 1997).

Legerski in US 6, 406, 891 B1 teaches a method for the synthesis of full length cDNAs utilizing a highly processive RNA-dependent DNA polymerase (see whole document especially col. 2, lines 32-56). He also teaches the use of RNA-dependent RNA polymerases (col. 21, lines 30-36), RNA-dependent DNA polymerase and DNA-dependent DNA polymerases (col. 9, lines 15-36) in the above method. He teaches MMLV and AMV reverse transcriptases (col. 7, lines 54-67). He teaches reverse transcribing RNA in the presence of processivity inhibiting structure (col. 2, lines 56-59). He teaches a polymerization composition having template nucleic acid, polymerase, and buffer (col. 13, lines 1-30).

Legerski in US 6, 406, 891 B1 does not teach binding proteins. He does not teach retroviral nucleocapsid RNA binding proteins. He does not teach NCp7. He does not teach reverse transcribing RNA in the presence of both inhibiting structures and increasing agents. He does not teach comparing the length of the polymerized products is measurably higher in the presence of the candidate agent than in the absence thereof. He does not teach a polymerization composition having a general RNA binding protein.

Allen et al in US 5, 654, 151 teach retroviral nucleocapsid RNA binding proteins increase the processivity of reverse transcriptase (col. 1, lines 45-67). They teach NCp7 (col. 20, lines 6-10). They teach reverse transcribing RNA where both inhibiting structures and increasing agents are present (col. 4, lines 33-45). They teach comparing the length of the polymerized products is measurably higher in the presence of the candidate agent than in the absence thereof

(col. 5, lines 15-66). They teach a polymerization composition having a general RNA binding protein (col8, lines 25-67).

One of ordinary skill at the time the invention was made would have been motivated to apply Allen et al's US 5, 654, 151 RNA binding proteins to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive RNA-dependent DNA polymerases in order to enhance processivity by over two orders of magnitude (col. 1, lines 50-65). It would have been prima facie obvious to apply Allen et al's US 5, 654, 151 RNA binding proteins to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive RNA-dependent DNA polymerases in order to enhance processivity by over two orders of magnitude.

6. Claims 13 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legerski (US 6, 406, 891 B1 June 18, 2002) in view of Allen et al (US 5, 654, 151 August 5, 1997) and in further view of Sampson et al (US 6, 054, 274 April 25, 2000).

The teachings of Legerski in US 6, 406, 891 B1 and Allen et al in US 5, 654, 151 have been described previously.

Legerski in US 6, 406, 891 B1 and Allen et al in US 5, 654, 151 do not teach flWT1(GNRA)2.

Sampson et al in US 6, 054, 274 teach flWT1(GNRA)2 (col. 8, lines 56-67).

One of ordinary skill at the time the invention was made would have been motivated to apply Sampson et al's US 6, 054, 274 flWT1(GNRA)2 to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive RNA-dependent DNA

polymerases in order to have a starting analyte for reverse transcription (col. 1, lines 31-40). It would have been prima facie obvious to apply Sampson et al's US 6, 054, 274 flWT1(GNRA)2 to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive RNA-dependent DNA polymerases in order to have a starting analyte for reverse transcription

7. Claims 22-28 & 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legerski (US 6, 406, 891 B1 June 18, 2002) in view of Tabor et al (US 5, 266, 466 November 30 , 1993).

The teachings of Legerski in US 6, 406, 891 B1 have been described previously. He also teaches T7 DNA polymerase (col. 13, lines 1-16).

Legerski in US 6, 406, 891 B1 does not teach single-strand DNA binding protein.

Tabor et al in US 5, 266, 466 teach single-strand DNA binding protein (col. 4, lines 34-53). They also teach T7 DNA polymerase (col. 7, lines 17-37).

One of ordinary skill at the time the invention was made would have been motivated to apply Tabor et al in US 5, 266, 466 single-strand DNA binding proteins to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive DNA-dependent DNA polymerases in order to enhance processivity by over two orders to greatly enhance processivity (col. 4, lines 34-53). It would have been prima facie obvious to apply Tabor et al in US 5, 266, 466 single-strand DNA binding proteins to Legerski's US 6, 406, 891 B1 method for the synthesis of full length cDNAs utilizing highly processive DNA-dependent

DNA polymerases in order to enhance processivity by over two orders to greatly enhance processivity.

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogrefe (US 6, 183, 997 B1 February 6, 2001).

Hogrefe (US 6, 183, 997 B1) teaches a method of selecting an agent which is capable of increasing the processivity of a DNA-dependent polymerase comprising an incubation of a candidate polymerase with a polymerization mixture and comparing the PCR product yields (col. 11, lines 1-11). Hogrefe also teaches nucleic acid replication reactions by providing length yields. (col. 3, lines 29-37) measuring

One of ordinary skill at the time the invention was made would have been motivated to modify Hogrefe (US 6, 183, 997 B1) method of selecting an agent which is capable of increasing the processivity of a DNA-dependent polymerase to include the length of the PCR product yield. It would have been prima facie obvious to modify Hogrefe (US 6, 183, 997 B1) method of selecting an agent which is capable of increasing the processivity of a DNA-dependent polymerase to include the length of the PCR product yield.

SUMMARY

9. No claims allowed.

CONCLUSION

10 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

July 25, 2002

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
7/29/02